IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to all cases.	

PSC'S PROPOSAL FOR
INITIAL ABBVIE-ONLY BELLWETHER TRIAL CASES

I. INTRODUCTION

Pursuant to Section II.B of the Third Amended Case Management Order No. 14 dated May 3, 2016 (Dkt. No. 1287), the Plaintiffs' Steering Committee (the "PSC") submits the following in support of selection of the six most instructive and representative cases for bellwether trials. The PSC has also provided a brief description of the remaining 18 unselected cases, and the reasons that they were not selected as instructive or representative and, accordingly, should not be selected for a bellwether trial.[1]

As discussed below, the PSC respectfully submits that the facts and circumstances of the six cases proposed by the PSC herein for early trial will best serve the purposes of the bellwether process by informing the Court, Defendants, and Plaintiffs about both common and relevant issues in this litigation, including, among others, those relating to liability, causation, alternative causation, product usage, and damages.

The purpose of selecting initial trial cases from a large pool of bellwether discovery cases

[1] As set forth in greater detail below, the original pool of 32 designated bellwether discovery cases has now been decreased, either by agreement and/or Court order, to 24 eligible cases. These 24 cases are listed on Exhibit A hereto, and the eight excluded case are listed on Exhibit B hereto.

is to learn and test general issues for the benefit of all—the Court, Plaintiffs, and Defendants. There are several significant issues, and those cases that have the most representative facts, and that do not turn on case-specific issues, should be selected to serve as the initial trial cases, as they will prove most instructive to the litigation as a whole. As noted below, the PSC has selected cases that meet and fit these goals.

The PSC has not proposed cases on the basis that they are the "best" for the Plaintiffs, and the PSC has not selected only those cases with the largest damages or most sensational injuries. While those types of cases might be desirable in the context of trying a single case, their selection would not achieve the goal for trying representative cases that will be instructive on the overall process and litigation for all of the cases in the MDL.

The PSC does not know which cases AbbVie will propose for the six initial trial cases. However, the PSC's experience in bellwether selection processes in other but similar cases is that defendants frequently put forward cases for which they can (a) obtain a dismissal prior to trial, and thus avoid trial; (b) present a unique alternative causation issue; (c) highlight a litany of alternative causation factors, whether or not they are reasonable, to give rise to jury arguments framed around the overall negative health of the plaintiff (or its related cousin, that "Mr. Smith was a heart attack/stroke/PE waiting to happen"), or (d) point to some personal or medical factor unique to the particular plaintiff, which often carries with it negative social or medical connotations (*e.g.*, morbid obesity, illegal drug use, etc.). The PSC understands both side's desire to win any given case or trial. But the purpose of the bellwether trial process is only served when representative cases are presented and tried, thus providing the guidance and instruction for thousands of other cases in the litigation. Accordingly, those cases that are factually or legally unique should not be selected.

The objective of this process is to learn overall information and test those cross-cutting issues alleged in the master complaint, including, among others, Plaintiffs' core liability theories in negligence, strict products liability (failure to warn and design defect), and general causation for the primary injuries pursued in this MDL. Trial of the core liability theories in several representative bellwether trials allows issues of notice of risks, and response to such notice; the sufficiency, accuracy, and adequacy of the product's claims, warnings, and instructions; company communications with and promotion to the medical community and patients concerning the same; and the product's risk and utility as promoted or used to be examined various contexts and over time. Similarly, with regard to general causation, presenting the issue to juries through representative trial cases allows the parties to see clear patterns in what the evidence directs with regard to the general causation question, *e.g.,* "Can AndroGel be a substantial factor in the development of a myocardial infarction in a male?" Cases presenting highly specific alternative causes, significant pre-existing or pre-disposing medical conditions, and/or prior similar injuries jeopardize the ability to inform the parties on the answer to that question. Of great concern, such cases present a serious risk of shifting the focus to unique and specialized issues instead of the global issues. The consequence: neither the parties nor the Court get the general information applicable to all cases that the bellwether process seeks to achieve.

As such, the PSC respectfully requests that the Court select the cases proposed by the PSC herein as the bellwether trial cases pursuant to CMO No. 14.

II. NATURE OF THE CASES

A. Summary of Claims

As the Court is aware, this MDL involves over 6,000 cases against several manufactures of prescription testosterone products, and over 5,000 cases pending against AbbVie for injuries

caused by AbbVie's AndroGel brand product. Plaintiffs in the Master Complaint allege several state-law causes of action, including strict products liability (based on theories of design defect and failure to warn), negligence, breach of warranty, fraud, unjust enrichment, and wrongful death, among others.

There are two general categories of injuries that Plaintiffs have suffered and attribute to AndroGel use; (i) cardiovascular injuries (*e.g.*, myocardial infarction), which involve events in the body's arterial system; and (ii) clotting injuries that involve the venous system (*e.g.*, deep vein thrombosis ("DVT") and pulmonary embolism ("PE")). Indeed, these two general categories of injury formed the basis of the original CMO 14, and all of its amendments, for the grouping and designating of these cases into injury categories.

To this end, below is an overview of these injury categories.

1. Cardiovascular Injury Cases

The primary cardiovascular injury alleged and at issue in this MDL is the heart attack. Acute myocardial infarction or "AMI" or "MI" (in layman's terms, "heart attack") occurs when a blood clot completely obstructs a coronary artery supplying blood to the heart muscle ventricle.[2] This results in necrosis (or cell death) of myocardial tissue if the occlusion persists for approximately 20 or more minutes.[3] The blood clot or "thrombus" that causes the heart attack usually forms at the site of rupture of an atherosclerotic, cholesterol-rich plaque on the inner wall

[2] *See* Thygesen, K., et al. *Universal Definition of Myocardial Infarction: on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction*; JACC Vol. 50, No. 22; 2007:2173–95, noting that the term "myocardial infarction" should be used only when there is evidence of myocardial necrosis in a clinical setting.

[3] http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/acute-myocardial-infarction/

of a coronary artery.[4] Myocardial infarctions can affect the anterior, inferior, or posterior walls of the heart but usually involve the largest heart muscle, the left ventricle.

The severity of an AMI depends on three factors: (1) the location of the occlusion in the specific coronary artery; (2) the length of time before the occlusion is relieved; and (3) whether adequate collateral arterial circulation has developed to compensate for the acute blockage in one or more of the main coronary arteries.[5] Diagnosis of myocardial infarction (sometimes termed "myocardial ischemia") is often based upon the combination of clinical presentation, the presence or absence of certain cardiac enzymes released into the circulating blood (*e.g.*, troponin), electrocardiographic findings, and cardiac imaging. These can also be used in conjunction with interventional procedures such as angiography/angioplasty.[6]

Certain risk factors may enhance the potential for an AMI by causing damage to the inner lining of the coronary arteries (atherosclerosis), and include: tobacco smoke; diabetes; hypertension (high blood pressure); problematic blood lipids (high cholesterol, high triglycerides, elevation of low density lipoproteins (LDL); and obesity.[7] These risk factors may worsen later in life such that AMI is uncommon under age 50; however, AMI may occur in younger individuals (<50 years) especially when there is an acquired increase in the tendency to form clots, termed hypercoagulability. AMI may occur in the context of antiphospholipid

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[4] *Id. See also* Davies, MJ; *Plaque fissuring—the cause of acute myocardial infarction, sudden ischemic death and crescendo angina;* Br. Heart J. 1985; 53:363-73

[5] http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/acute-myocardial-infarction/

[6] *Id.*

[7] http://www.mayoclinic.org/diseases-conditions/myocardial-ischemia/basics/risk-factors/con-20035096; *See also,* Thygesen, K., et al. *Universal Definition of Myocardial Infarction: on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction*; JACC Vol. 50, No. 22; 2007:2173–955

antibody (APLA) syndrome[8], malignancy, or other hypercoagulable states that include, among others, exposure to exogenous hormones, *e.g.*, oral contraceptives,[9] and hormone replacement therapy.[10]

Clinical symptoms associated with AMI or heart attack, are the result of cardiac ischemia (cellular death), and patients may present with discomfort of the chest, upper extremity, jaw, or epigastrium, either with exertion or at rest.[11] The discomfort can be prolonged, and diffuse instead of localized; the pain generally cannot be relieved by changing position and is often accompanied by shortness of breath, excessive sweating, feeling faint, or even loss consciousness.[12]

The occurrence of myocardial infarction is often a life-changing event if the patient survives it. Dramatic presentations with sudden development of dysfunction and/or pain emanating from the involved organ, e.g. heart failure and/or angina are not uncommon for AMI. Later manifestations of cardiovascular disease as complications of AMI can include congestive heart failure, atrial fibrillation and other arrhythmias, sudden death, and peripheral embolism. Sudden death can also result from AMI, often with little or no warning with myocardial

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[8] Shanahan, J.C.; *Antiphospholipid Antibodies and Stroke; Seminars in Cerebrovascular Diseases and Stroke*; 2(2); 2002:120-133.

[9] Baillargeon, JP; McClish, DK; Essah, PA; Nestler JE; *Association between the current use of low-dose oral contraceptives and cardiovascular arterial disease: a meta-analysis;* J. Clin Endocrin & Metabol. 2005; 90 (7): 3863-3870.

[10] Women's Health Initiative Investigators (Writing Group); *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women Principal Results From the Women's Health Initiative Randomized Controlled Trial; WHI Study*: JAMA; 2002; 288(3):321- 333.

[11] Thygesen, K., et al. *Universal Definition of Myocardial Infarction: on behalf of the Joint ESC/CCF/AHA/WHF Task Force for the Redefinition of Myocardial Infarction*; JACC Vol. 50, No. 22; 2007:2173–955

[12] *Id*.

infarction considered to be a major cause of death and disability worldwide.[13]

Another cardiovascular event that has been alleged in the litigation is ischemic stroke. Ischemic stroke is a type of neurologic injury that results from a transient or permanent reduction in cerebral blood flow to the territory supplied by a major brain artery, and is usually the result of occlusion (acute blockage) of a cerebral artery, either by an embolus traveling up into the head or by local thrombosis.[14] In an ischemic stroke, the interruption of blood flow causes oxygen starvation in an area of the brain; this cellular injury pattern is known as cerebral ischemia.[15] This blood flow blockage causes the same type of cellular death that occurs in acute myocardial infarction.

An acute ischemic stroke typically presents as a sudden onset of symptomatic focal neurologic findings, including difficulty speaking and/or word finding, visual deficits, paralysis such as inability to walk or keep balance, or inability to feel certain parts of the body. These findings are usually confined to one side of the body, and the clinical manifestations depend upon the side and area of the brain that suffers ischemic damage.

Risk factors for ischemic stroke mirror those that increase the risk of atherosclerosis in the coronary vessels, and in this case cause atherosclerosis in both the large cerebral arteries and small cerebral arteries. These common risk factors include: tobacco use, high blood pressure

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[13] Moran, AE; *The Global Burden of Ischemic Heart Disease in 1990 and 2010 The Global Burden of Disease 2010 Study*; Circulation. 2014 April 8; 129(14): 1493–1501.

[14] Dirnagl U. et al.; *Pathobiology of ischaemic stroke: an integrated view.* Trends Neurosci 1999; 22: 391-7.

[15] Lopez AD. Et al. *Global and regional burden of disease and risk factors, 2001: systematic analysis of population health data.* Lancet 2006; 367: 1747-57; Feigin VL, Lawes CM, Bennett DA, Anderson CS. Stroke epidemiology: *a review of population-based studies of incidence, prevalence, and case-fatality in the late 20th century*. Lancet Neural. 2003; 2: 43-53. American Heart Association Stroke Statistics, 2014.

(hypertension), high blood lipid levels (*e.g.* hypercholesterolemia), diabetes mellitus, and obesity.[16]

Like myocardial infarction, ischemic stroke may also result from the acquisition of a hypercoagulable process,[17] malignancy, or other hypercoagulable states[18] that include, among others, exposure to exogenous hormones (*e.g.*, oral contraceptives; hormone replacement therapy).[19] Disorders of abnormal red blood cell flow within the cerebral vessels, *e.g.*, sickle cell disease[20] and polycythemia[21], also greatly increase the risk of ischemic stroke.

Ischemic stroke is often associated with severe disability and physical limitation. In the wake of a stroke, some or all of the following manifestations may be acutely present: paralysis, aphasia, neurocognitive impairment, and/or headache, as well as more subtle neurologic and/or psychological abnormalities related to the exact location of the stroke. Subsequent complications of ischemic stroke include but are not limited to: dementia or other neurocognitive impairment, psychiatric illness, non-neurologic physical degeneration related to immobility, loss of bladder/bowel control, and infection.

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[16] Dirnagl U., et.al; Pathobiology *of ischaemic stroke: an integrated view*. Trends Neurosci 1999; 22: 391-7.

[17] Shanahan, J.C.; *Antiphospholipid Antibodies and Stroke; Seminars in Cerebrovascular Diseases and Stroke*; 2(2); 2002:120-133.

[18] Bushnell, CD; *Diagnostic Testing for Coagulopathies in Patients with Ischemic Stroke;* Stroke; 2000(12):3067-78.

[19] Oral contraceptives, containing estrogen (ethinyl estradiol), have been implicated for a decade or more in the etiology of thrombotic stroke. *See, e.g.,* Godsland IF, et al.; *Occlusive vascular diseases in oral* contraceptive *users.* Epidemiology, pathology and mechanisms. Drugs. 2000; 60(4):721- 869; Bushnell, CD; *Oestrogen and stroke in Women*; The Lancet; 2005; 4(11):743–751.

[20] van der Worp HB, van Gijn J. *Acute lschemic Stroke*. N Engl J Med 2007; 357: 572-9.

[21] Hart, R.G., et. al.; *Hematologic Disorders and Ischemic Stroke: a selective review;* Stroke. 1990:21:1111-1112.

In the case of both AMI and ischemic stroke, analogous medical therapies are employed to prevent initial or recurrent AMI or ischemic stroke, including measures to reduce blood lipid levels and atherosclerosis (*e.g.*, statins) and to reduce the propensity to form arterial clots by blocking platelet function (*e.g.*, aspirin, clopidogrel, prasugral), especially after angioplasty or stent placement.

2. Venous Thromboembolism (DVT/PE)

Deep vein thrombosis (DVT) and pulmonary embolism (PE) comprise the category of venous thromboembolism (VTE). A DVT is a thrombus or blood clot that forms in the large veins (unlike the arteries in AMI and ischemic stroke), usually the deep veins of the legs, and less often the pelvis.[22] DVT is adherent to the vessel wall and prevents blood from flowing back to the heart, trapping the blood and causing swelling and pain. If the clot breaks off and travels through the venous circulation up to (and then trapped within) the lungs, a PE occurs. The PE cuts off blood circulation to parts of the lung tissue, killing lung tissue and thereby decreasing the oxygen content of the blood; the extent of damage is driven by the size and number of the clots.

In young patients (<50 years), the overall incidence of VTE is relatively low, with an annual risk estimated to be near 5/100,000. In older age individuals, the incidence of VTE rises steadily after age 55 such that the overall incidence is nearly 100-fold higher than in patients 45 years or younger.[23]

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[22] Other less commonly reported venous thrombotic events include cerebral sinus thrombosis, retinal vein thrombosis and thrombosis of major abdominal veins such portal, hepatic, renal vein and vena cava.

[23] Silverstein, RL, et. al; *Venous thrombosis in the elderly: more questions than answers*; Blood; 2007; 110(9): 3097-3101.

VTE has a well-described pathophysiology that is often said to consist of three elements (Virchow's triad).[24] (1) Alterations in blood flow: e.g., from prolonged immobility, including long-haul air travel or prolonged bed rest due to surgical procedures or medical illness; diseases of the heart including heart failure; or pregnancy, from gravid uterus compression of pelvic veins. (2) Damage to blood vessels: e.g., from surgery, especially in the lower extremities; trauma; or when a previous venous thrombus distorts normal venous blood return. (3) Abnormal predisposition to form clots (thrombophilia): this refers to hypercoagulability due to either (a) inherited; or (b) acquired conditions described below:

- *Inherited* thrombophilias are genetic defects which include Activated Protein C resistance due to factor V Leiden, abnormalities leading to deficiencies of the natural anticoagulants protein C, protein S, and antithrombin, and the prothrombin G20210A mutation.

- *Acquired* thrombophilias include APLA syndrome, (both lupus anticoagulants and/or anticardiolipin antibodies), malignancies, endogenous hormone changes (pregnancy), and exogenous hormone administration (e.g., combined oral contraceptives and estrogen containing hormone replacement therapies).[25] Polycythemia (disease state in which the proportion of blood

[24] Virchow RLK *Gesammelte Abhandlungen zur wissenschaftlichen Medicin*. Frankfurt am Main, Germany: Von Meidinger & Sohn; 1856. English translation: Matzdorff AC, Bell WR. *Thrombosis and Emboli*. Canton, MA: Science History Publications; 1998R.

[25] Rosendaal FR, et al; Estrogens, progestogens and thrombosis. J Thromb Haemost; 2003; 1: 1371; Women's Health Initiative Investigators (Writing Group); *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women Principal Results From the Women's Health Initiative Randomized Controlled Trial; WHI Study*: JAMA; 2002; 288(3):321- 333. *See also,* Dahlback B. *Inherited thrombophilia: resistance to activated protein C as a pathogenic factor of venous thromboembolism.* Blood; 1995; 85:607. An increase in activated protein C resistance (APC-R), as seen in women exposed to exogenous estradiol, is one of the most prevalent risk factors for excess thrombin generation and has been strongly implicated in the pathogenesis of venous thromboembolic disease. Dahlback B. *Inherited thrombophilia: resistance to activated protein C as a pathogenic factor of venous thromboembolism.* Blood; 1995; 85:607.

volume that is occupied by red blood cells increases above normal levels) may also predispose an individual to excessive clotting risk.[26]

It is widely believed that there is an additive or synergistic effect for all of the risk factors associated with thrombosis, such that the clotting risk is higher in individuals with multiple simultaneous risk factors.[27]

VTE is a serious and potentially life-threatening condition. DVTs can be clinically silent without symptoms, or it can present with pain, warmth, redness, and swelling in the involved extremity although imaging studies may not always reveal the presence of blood clots in the legs. DVT is difficult to diagnose by physical examination alone and requires imaging and laboratory studies. A PE can also be silent but is more likely to present with chest pain or shortness of breath[28] and can even cause sudden death. When DVT resides in the thigh, the patient is at especially increased risk for the clot to break off and cause PE.

All DVT patients should receive full-dose anticoagulation to resolve the clot and prevent recurrence. In the case of a provoked VTE with a single risk factor, e.g. following a fracture or surgery, anticoagulation may be discontinued after 3-6 months of therapy. During

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[26] Vayá, A; et al; *Biological risk factors for deep vein thrombosis: The 11th European Symposium on Clinical Hemorheology,* Clinical Hemorheology and Microcirculation 26 (2002) 41–53 41

[27] *See, e.g.,* Rosendaal FR. *Factor V Leiden (Resistance to activated protein C) increases the risk of myocardial infarction in young women*. N Engl J Med 1997:89:2817. Mannucci PM, e al.; *the association of factor V Leiden with myocardial infarction is replicated in 1880 patients with premature disease*. J Thrombi Headmost 2010; 8:2116–21. Pomp, et al., *Smoking increases the risk of venous thrombosis and acts synergistically with oral contraceptive use*, Am. J. of Hematology, 83:97-102 (2008).

[28] Other less commonly reported venous thrombotic events include cerebral sinus thrombosis, retinal vein thrombosis and thrombosis of major abdominal veins such portal, hepatic, renal vein and vena cava.

anticoagulation, patients may require periodic monitoring, depending upon the specific therapy, to assure efficacy without excess bleeding risk. Unlike therapy to reduce atherosclerosis in the vessels of the heart and brain, long-term abrogation of risk factors, e.g. avoidance of hormone therapy, is the mainstay for minimize risk or recurrent VTE. However, depending upon the clinical history and severity of the thrombosis, lifetime anticoagulation, even with its attendant bleeding risks, is often indicated.

III. BELLWETHER PROCESS TO DATE

A. History CMO 14 and Discovery Efforts

As the Court is aware, CMO No. 14 governs the AbbVie-only initial trial schedule and case-selection process. At AbbVie's instance, following briefing and argument at several case management conferences, that CMO has been amended three times. The original CMO No. 14 (Dkt. No. 467) was entered on November 6, 2014. The first Amended CMO No. 14 (Dkt. No. 793) was entered on May 29, 2015. The Second Amended CMO No. 14 was entered December 10, 2015. The latest version, Third Amended CMO No. 14 was entered on May 3, 2016.

Pursuant to Amended CMO 14, the parties submitted their initial 32 bellwether picks on October 31, 2015, and that pool has been reduced to 24 cases (*see* Ex. A hereto, listing the 24 cases remaining in the pool, and Ex. B hereto, listing the cases omitted from the pool). Core discovery in these 32 cases commenced on December 1, 2015. The parties have been working diligently to proceed in these cases concurrently. As a result, 24 plaintiffs have been deposed. Approximately 25 of plaintiffs' doctors have been deposed. Approximately 30 of AbbVie's current and former sales representative assigned to detail Plaintiffs' doctors have been taken. Over 40 custodial files of sales representatives have been produced and reviewed, and records from hundreds of healthcare and medical providers have been obtained and reviewed.

B. Number and Order of Initial Trials

The last two versions of CMO No. 14 left open to this submission the number and order of the initial trials. As set forth below, however, the PSC respectfully submits that identifying and setting six (6) cases for trial satisfies the goals of this bellwether program and will sufficiently inform the Court and the parties about the issues that the bellwether program was established to test.

1. Number of Bellwethers/Initial Trials

As noted, with the most recent amended CMO No. 14, the Court reserved to this point in the process the number of Abbvie-only bellwether trials to be scheduled at this time. The initial CMO No. 14 provided for the selection by the Court of bellwether cases for six trials. The most recent amended CMO No. 14 provides for the selection of "up to 8" bellwethers for these early trials. *Compare* CMO No. 14 § II.C (Dkt. No. 467) (providing that "the Court will select which bellwether cases are to serve as the first three TE trials and which are to serve as the first three cardiovascular trials and shall designate the order of these bellwether trials"), *with* Am. CMO No. 14 § II.C (Dkt. No. 793) (same), *and* 2d Am. CMO No. 14 § II.C (Dkt. No. 1089) (stating "the Court will select up to twelve (12) bellwether cases to serve as the first bellwether trial cases and shall designate the order of these bellwether trials"), *and* 3d Am. CMO No. 13 § II.C (Dkt. No. 1287) (stating "the Court will select up to eight (8) bellwether cases to serve as the first bellwether trial cases and shall designate the order of these bellwether trials").

The original CMO No. 14 and all amended versions, through their detailed dates, always reflected only six trial settings. The PSC submits this is for good reason. As a threshold matter, each of the six MDL bellwether trials represents a substantial undertaking, *e.g.,* full case-specific fact discovery for trial, case-specific expert disclosures and discovery, pre-trial motion

practice—both dispositive and *in limine*, deposition designations/counters/objections, together with all that a complex pharmaceutical products liability trial otherwise involves. Indicative of that undertaking, the schedule for the six scheduled trials already goes into early 2018.[29] While it is possible that more AbbVie-only trials could prove necessary, the PSC maintains that setting further trials, or drawing further bellwethers into a pool for such trials, at this point, is premature. The PSC submits that leaving further trials unscheduled provides the Court and the parties flexibility to better (or supplementally) address legal, scientific, or liability issues identified in the early AbbVie-only bellwethers trials. Further, beyond the instant trial-eligible pool of bellwether cases, the mixed-used AndroGel cases represent a non-trivial component of the docket that the Court and parties may wish to consider for future bellwether trials as information is developed from the AbbVie-only trials.

Thinking more broadly, beyond AbbVie, it will also be instructive to the litigation to schedule trials against other manufacturers. The first trial against Eli Lilly & Co, has been proposed to occur in January, 2018, just after the sixth AbbVie trial. Accordingly, the PSC maintains that the identification of six AbbVie-only trial bellwethers is both reasonable and prudent. Should a need become apparent to set additional AbbVie-only cases for trial, the Court, with the parties' support, could do so on a rolling basis as the need arises.

2. Order of Initial Trials

While the first two versions of CMO No. 14 contemplated that venous clot injuries would be tried first (PE/DVT cases), the last two versions abandoned that concept. As the litigation has

[29] While the PSC does not know how many cases AbbVie will now advocate the Court should select, the PSC submits that AbbVie's repeated extension requests and discovery challenges in the bellwether process to date further augur against going beyond the six trials currently scheduled into 2018.

evolved (subsequent to the initial version of CMO No. 14 in November 2014), it became apparent that the predominant injury claimed in this litigation is cardiovascular. Within that broader cardiovascular injury group, the specific injury of myocardial infarction overwhelmingly predominates. Accordingly, the PSC proposes that cases involving cardiovascular injuries—specifically, MI—be tried first.

IV. PLAINTIFFS' PROPOSED TRIAL CASES

A. Purpose of Bellwether Process

As noted above, to ensure that the bellwether process is effective for the evaluation of as many cases as possible, it is important that the cases selected for trial do not have atypical case-specific, or unique legal and/or factual issues particular to a given plaintiff. Such scenarios will not benefit the Court or the parties if a unique fact or series of facts raise the possibility of dismissal or a directed verdict. To avoid inefficient expenditures of time, personnel and financial resources by the Court and the parties, and to further the purposes of the bellwether process, the cases selected for trial should not be littered with unusual case sensitive facts or unique issues of law. To be truly representative of the larger pool of cases in this litigation, the bellwether trial cases should not have unusual or unique conditions that Defendants can use to either complicate questions of Defendants' liability, confound causation issues, or the degree of damages the Plaintiff suffered. Atypical medical and social history should also be avoided in the ultimate trial case selections.

B. Case Summaries of Plaintiffs' Proposed Six (6) Cases

The PSC proposes, on behalf of Plaintiffs, that the following six cases be selected as the first six bellwether trials:

(1) the *Deel* case, No. 1:14-CV-6996, as the first trial set to start on June 5, 2017;

(2) the *Konrad* case, No. 15-cv-00966, as the second trial set to start on July 17, 2017;

(3) the *Mitchell* case, No. 14-cv-09178, as the third trial set to start on August 28, 2017;

(4) the *Blanck* case, No. 15-cv-01077, as the fourth trial set to start on October 9, 2017;

(5) the *Myers* case, No. 15-cv-01056, as the fifth trial set to start on November 20, 2107; and

(6) the *Nolte* case, No. 14-cv-08135, as the sixth trial set to start on January 8, 2018.

Below please find a brief factual summary of each of Plaintiffs' six proposed cases:

1. Trial case No. 1: *David Deel*, No. 1:14-CV-6996:

Mr. Deel is a resident of Lancaster, Kentucky, and, at the time of his heart attack on January 16, 2014, he was a resident of Lexington, Kentucky. He used AndroGel from approximately September 5, 2008 to January 16, 2014 for erectile dysfunction and fatigue. Mr. Deel was 54 years old at the time of his heart attack. He used AndroGel without incident for several years, though his symptoms of erectile dysfunction and fatigue were not significantly improved. Throughout that time his hemoglobin and hematocrit levels elevated occasionally, but usually resolved.

In January 2014, while vacationing with his wife in Cozumel, Mexico, Mr. Deel began experiencing chest pains. Seeking relief for his pain, his wife went to the hotel front desk to get some aspirin, but was unsuccessful, so she had to go to a bodega a few blocks away. When she returned, Mr. Deel was incapacitated on the floor of his hotel room and in severe pain. There were no ambulances available and she had to take him to the nearest clinic in a taxi cab. The medical staff on duty could not speak English (and the Deels could not speak Spanish), and the initial treaters could not understand what the problem was or how to properly treat it. He was

ultimately diagnosed with a heart attack, and a bilingual doctor came on duty at shift change and advised the Deels to seek immediate treatment in an American hospital. Mr. Deel was medically evacuated to a hospital in San Antonio, Texas, where he remained for one week.

During a follow up doctor's appointment, upon returning to his home in Kentucky, it was discovered that Mr. Deel was suffering from ischemic cardiomyopathy as a consequence of his initial heart attack. Further, as a result of significant scarring incurred during the myocardial infarction, Mr. Deel developed severe ventricular tachycardia, which required multiple subsequent hospitalizations and ablation procedures. His ejection fracture is now approximately 30%, and he has been dealing with significant depression as a result of the prolonged and sustained effects of the heart attack.

Mr. Deel is now permanently disabled. He was forced to prematurely retire from his job as a truck driver for the postal service. He now has to rely on his wife for financial and emotional support, and she has understandably endured a significant emotional toll as well.

Mr. Deel has a history of hypertension and is a former smoker (quitting approximately 10 years prior to his heart attack). His height at time of his heart attack was 5'11", and he weighed approximately 231 lbs, and any risk factors for heart attack were not excessive or out of the ordinary for a typical man in his 50s, and seem to be fairly consistent with the population AbbVie targeted for AndroGel therapy. Mr. Deel's general health profile, as described above is very characteristic of plaintiffs in this litigation, who tend be of a comparable age of Mr. Deel who was 54 at the time of his MI.[30]

[30] AbbVie may try to argue, as it has previously unsuccessfully done, that Mr. Deel's case is unrepresentative because of a single knot in his medical records – that his urologist, Dr. Crowe, prescribed him Androderm once in 2008. However, it is evident that Mr. Deel never filled any such prescription. To the contrary, it is clear that Mr. Deel only ever used AndroGel. (footnote continues on next page)

Additionally, Mr. Deel's reasons for starting AndroGel (i.e. age related testosterone declines coupled with symptoms including fatigue and sexual dysfunction) are characteristic of plaintiffs in this litigation. Furthermore, Mr. Deel's had low testosterone levels, but they were typical for a man of his age, which also fits the usual pattern of what is seen with most AndroGel users.

This case is representative on a host of levels: (1) Plaintiff presents with risk factors that are common to the general population, as well as the pool of 24 eligible plaintiffs, including hypertension, which is present in approximately 15 of the 24 eligible cases; (2) Plaintiff has a history of smoking, which is present in approximately seven of the 24 eligible plaintiffs; (3) he does not have unique alternative causation factor; (4) Plaintiff used AndroGel for approximately five years prior to his injury, which is similar to seven of the 24 eligible plaintiffs who used AndroGel for greater than two years and four more who used it for longer than three years (likewise from the group of 100 cases 30 plaintiffs used AndroGel for longer than two years and 19 for three years or longer); and (5) Plaintiff was 54 years old at the time of his injury and 12 plaintiffs from the group of 24 cases were between ages 51-60 (and from the original pool of 100 plaintiffs, 38 were between the ages of 50 and 59).

Therefore, the PSC submits this case will be instructive on determining whether AndroGel may cause this kind of thrombotic event and should serve as an initial trial case.

2. <u>Trial case No. 2</u>: *Jeffrey Konrad,* No. 15-cv-00966:

Mr. Deel has testified repeatedly under oath that he never used Androderm, and his testimony is supported by his pharmacy records which do not identify Androderm as one of his prescription medications. Androderm is also not listed as an active medication in Dr. Crowe's medical records other than the single anomalous note referred to above. Furthermore, Dr. Crowe testified at his deposition that there is no indication in his records that Mr. Deel ever filled an Androderm prescription. As such, there is no real issue concerning mixed use in this case.

Mr. Konrad is a resident of Collierville, Tennessee. He suffered a myocardial infarction on July 9, 2010 at the age of 49. Mr. Konrad used AndroGel from approximately May 5, 2010 to July 10, 2010. Mr. Konrad is a manager at his family's transportation consulting business, Traffic Consultants, Inc., in Memphis, Tennessee.

On July 9, 2010, Mr. Konrad started experiencing shortness of breath and left arm and chest pressure after being on the treadmill for about 10 minutes. He went to Baptist Memorial Hospital-Collierville, and, after certain tests were completed, he was diagnosed with a heart attack and transferred to Baptist Memorial Hospital-Memphis, where he was hospitalized from July 9, 2010 to July 10, 2010. He required a left heart catheterization, left ventricular angiogram and insertion of a stent.

At the time of his injury, Mr. Konrad was 6' tall and weighed 250 lbs. While Mr. Konrad has a family history of heart attack and stroke, he has few other risk factors for his heart attack. He has no medical history of heart problems. Mr. Konrad is married to Jana Konrad who has asserted a loss of consortium claim.

While Mr. Konrad's usage of AndroGel was relatively short, a short duration usage case is representative of the overall pool of AndroGel plaintiff cases and litigating this issue would be instructive to hundreds, if not thousands of other cases where short duration of use is alleged before a MI.

Additionally, Mr. Konrad's age is representative of the average age of an AndroGel user as he is a middle-aged man who was experiencing an age-related decline in testosterone. He was of average health; although somewhat overweight, and only exercised on occasion (to lose weight).

As a result of Mr. Konrad's myocardial infarction he was hospitalized for two days,

during which time he underwent percutaneous coronary intervention with the placement of a stent, which is a common treatment for myocardial infarctions. As such, both his course of treatment and his less than catastrophic injuries make this a representative case that will provide great guidance for so many other myocardial infarction cases that may have greater damages (and perhaps less damages) as well as others that might have far more confounding factors.

In sum, this case is representative of the larger pool of cases for the following reasons: (1) Mr. Konrad used AndroGel for two months prior to his injury, which is similar to eight of the 24 (or one-third) of the eligible plaintiffs who used AndroGel for six months or less (and 32 of the 100 plaintiffs in the random bellwether pool used AndroGel for 8 months or less); (2) Mr. Konrad had a hospital stay of one day, which is similar to 12 of the 24 eligible plaintiffs who had hospital stays of three days or less; (3) Mr. Konrad is a non-smoker, which is a characteristic present in 17 of the 24 eligible plaintiffs; (4) Mr. Konrad has a family history of myocardial infarction, and likewise 11 of the 24 eligible plaintiffs have a family history of heart attack. Again, these factors will be very useful and instructive for many cases in the pool.

Therefore, the PSC submits this case will be instructive on determining whether AndroGel may cause this kind of thrombotic event and should serve as an initial trial case.

3. Trial case No. 3: *Jesse Mitchell*, No. 14-cv-09178:

Plaintiff, Jesse Mitchell is a resident of Portland, Oregon. He used AndroGel for over five years prior to his myocardial infarction, which took place on November 18, 2012, at the age of 49.

On November 18, 2012, as a result of his myocardial infarction, Mr. Mitchell was rushed to the hospital, where he was defibrillated and und underwent a successful thrombectomy, and placement of stents. His entire hospital stay lasted five days, two of which he was comatose. During his hospital stay, he also suffered kidney failure as a result of his myocardial infarction.

At the time of his myocardial infarction, Mr. Mitchell had a medical history that included smoking and hypertension, as well as a family history of hypertension and myocardial infarction.

The fact that Mr. Mitchell has the presence of *both* a family history of myocardial infarction and a history of hypertension is representative of the larger pool of cases, and trying a case where this synergism of two common risk factors is present will be instructive to many cases in this litigation. Further, his age is also representative of an average AndroGel user since he is a middle-aged man of average health.

Accordingly, Mr. Mitchell's case is representative of the larger pool of cases for the following reasons: (1) Mr. Mitchell has the presence of *both* a family history of myocardial infarction and a history of hypertension, and the simultaneous presence of these two factors is present in six of the 24 eligible cases; (2) Mr. Mitchell underwent placement of stents and suffered kidney failure as a result of his myocardial infarction, and substantially suffering as a result of myocardial infarctions is typical to myocardial infarction cases so the damages value of this case will be instructive to determining the value of myocardial infarction cases; and (3) Mr. Mitchell presented with a cardiac arrhythmia at the time of his myocardial infarction, and this fact will address a common issue in this litigation – whether the arrhythmia preceded the thrombosis or vice versa – and will be instructive for many cases in the pool. Further, the fact that this case was designated by both the PSC and AbbVie lends further support that this case is a representative one

4. **Trial case No. 4: Lance Blanck**, No. 15-cv-01077:

.Plaintiff, Lance Blanck, suffered a deep vein thrombosis ("DVT") and PE on December 24, 2013, when he was 59. He is a resident of South Lake Tahoe, California and is a retired TSA officer. His wife, Kim, complained that his libido was low. As such, Ms. Blanck spoke to a physician's assistant, Catherine Gaewiler, who was her coworker at the time, about Mr. Blanck's

lack of libido and energy. Ms. Gaewiler prescribed AndroGel 1%. Later, Mr. Blanck presented to his family doctor, Steven Brooks, MD, and informed him of his AndroGel use, and Dr. Brooks performed a blood test, and Dr. Brooks continued the AndroGel prescription.

Following his DVT and PE in December 2013, Mr. Blanck was treated with Xarelto for about six months. He was scheduled to have knee surgery prior to his DVT/PE, but he has elected not to go forward with that procedure, at least in part due to his risk of PE. Dr. Brooks testified that he would have expected that there would be a warning on the label if there was a VTE risk, and that he would want to know about that risk and discuss it with his patients.

As noted above, this case is representative of the larger pool of cases for the following reasons: (1) Plaintiff presents with risk factors that are common to the general population, as well as the pool of 24 eligible plaintiffs, including hypertension, which is present in approximately 15 of the 24 eligible cases; (2) he does not have unique alternative causation factor; and (5) Plaintiff was 54 years old at the time of his injury, 12 plaintiffs from the group of 24 cases were between ages 51-60, and from the original pool of 100 plaintiffs, 38 were between the ages of 50 and 59. Mr. Blanck's case is thus representative of the plaintiff pool, and these factors will be very useful and instructive for many cases in the pool.

5. Trial case No. 5: Arthur Jeffrey Myers, No. 15-cv-01056:

Plaintiff, Jeffrey Myers, is a resident of Prescott Valley, Arizona. Mr. Myers suffered bilateral pulmonary emboli ("PE") on February 6, 2008. Mr. Myers was prescribed AndroGel in 2003. At the time, Mr. Myers was a restaurant manager. He had presented to his primary care physician and requested a prescription for AndroGel because one of his friends had told him that it would enhance his sexual performance. Mr. Myers, then 38 years old, sought to increase his libido and sexual performance. Mr. Myers felt that the AndoGel was effective and did increase his sexual performance. While there may have been some gaps in his use of AndroGel, and Mr.

Myers may have decreased his dosage at times, he was using AndroGel when he suffered a bilateral PE on February 6, 2008.

On that date, Mr. Myers was golfing with friends when he became short of breath. His friends remarked that he looked pale and unwell. Mr. Myers presented to a nearby hospital, where he underwent an EKG that came back abnormal. He was diagnosed with exertional dyspnea and pulmonary hypertension, and a CT scan was ordered to investigate the possibility of PE. Mr. Myers was admitted to the hospital, but there was a delay in performing the chest CT. He then left the hospital against medical advice: (1) because of the delay; (2) because the hospital was out of his healthcare network (and he would have to pay more of the cost of the CT scan); and (3) because he felt well enough to go home. He went home and slept and then, on the following day, he presented to a hospital closer to his home, where he was formally diagnosed with bilateral PE.

Mr. Myers was discharged on Coumadin, which he took for approximately six months. He was also discharged on AndroGel, and he was never told to discontinue the AndroGel. Mr. Myers continued to use AndroGel until September 2008, when his wife became pregnant. Mr. Myers finally discontinued AndroGel because he felt it was no longer needed with changes to his lifestyle and because of transference risk.

Mr. Myers' case is representative of the larger pool of cases for the following reasons: (1) Mr. Myers represents the typical AndroGel patient that is prescribed AndroGel because both the plaintiff and prescriber believed it would improve sexual function, and as such will be instructive on this marketing aspect of the case; and (2) Mr. Myers was 38 years old when he was prescribed AndroGel, and this is representative of plaintiffs who received AndroGel prescriptions at a relatively young age, which is reflected by the fact that approximately 25% of the 100 random

plaintiffs as well as 25% of the 24 eligible plaintiffs suffered their injury before they were age 50.

6. Trial case No. 6: Robert Nolte, No. 14-cv-08135:

Mr. Nolte is a resident of Sierra Vista, Arizona. He suffered a PE on November 1, 2012, at the age of 72. Mr. Nolte used AndroGel for approximately three months prior to his injury.

On the day of his injury, Mr. Nolte experienced left-sided spasm at the bottom of his rib cage with shortness of breath. He went to Sierra Vista Hospital, where he was diagnosed with bilateral pulmonary emboli and transported to University of Arizona Medical Center in Tucson for further management. He was hospitalized from November 1, 2012 to November 4, 2012. While in the hospital, he was treated with Coumadin and Lovenox, and anticoagulation medication was continued after discharge.

Mr. Nolte's height at time of injury was 5'6", and he weighed 180 lbs. He has a history of smoking from 1956 to 2009, hypertension in 2011, genetic blood clotting disorder (Factor V Leiden), PE and cancer.

Mr. Nolte was diagnosed with hypertension approximately in 2011. He was diagnosed with Factor V Leiden approximately in February 2011, following a diagnosis of Pulmonary Embolism. He was also diagnosed with bladder cancer in June 2009 and has a family history of blood clots in the legs, lungs, or eyes from his mother.

As noted above, this case is representative of the larger pool of cases for the following reasons: (1) Mr. Nolte suffers from Factor V Leiden, the most common form of inherited thrombophilia, accounting for approximately 40%-50% of inherited thrombophilia;[31] (2) Plaintiff

[31] Kujovich, Jody Lynn. "Factor v Leiden thrombophilia." *Genetics in Medicine*13.1 (2011): 1-16.

was 72 years old at the time of his injury, and 20 of the original 100 random plaintiffs were over age 65, and seven of the 24 eligible plaintiffs are age 60 or over; and (3) Mr. Nolte suffered a prior PE, and approximately 18% of the cases from the pool of 100 had a documented prior event prior to their event on AndroGel.

C. Case Summaries of Remaining 18 Omitted Cases

The PSC respectfully submits that the Court should not select the following 18 remaining cases as initial trial cases. These cases[32] are not suited to serve as bellwether trial cases because, although they present meritorious claims, they all have one or more factors and unique circumstances and issues that render them atypical, unnecessarily complicated or not instructive for the thousands of other cases in this MDL.

1. Richard Cannon, Sr., No. 15-cv-01484:

Mr. Cannon is represented by Onder, Shelton, O'Leary & Peterson LLC. Plaintiff suffered a DVT on March 26, 2014. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

First and foremost, Mr. Cannon may have been inappropriately prescribed AndroGel by his prescribing physician, Dr. Donald Donna, raising a unique issue with his doctor.[33] This will inject an unnecessary layer of complexity into the case, compromising the instructiveness of this case on the key issue in this litigation, namely, whether AndroGel causes venous thrombotic

[32] The cases are listed in alphabetical order.

[33] According to Mr. Cannon's medical records, his laboratory results showed that his total testosterone levels were 350 ng/dl, within the normal range, prior to initiating AndroGel. At trial, AbbVie will likely make an issue of this, claiming that AndroGel should never have been prescribed to someone with normal testosterone levels, and that therefore Mr. Cannon's injury, if caused by his AndroGel, was due to the negligence of Dr. Donna in inappropriately prescribing him AndroGel in the first place.

events.

Second, Mr. Cannon's case involves more than a typical number of confounding factors that render this case non-representative. Further, prior to suffering his DVT, Mr. Cannon took an extended plane trip from Louisiana to Puerto Rico, and a subsequent approximately 8 to 10 hour car ride. This extended period of immobility is not characteristic of the pool of plaintiffs as a whole, and will again likely be pointed to by AbbVie as one of many alternative causes of Mr. Cannon's injury other than AndroGel, thus rendering this case uninstructive for determining the causal nexus between AndroGel and DVTs.

2. Edward Cribbs, No. 15-cv-01056:

Mr. Cribbs is represented by Weitz & Luxenberg, P.C. Plaintiff suffered a MI on May 25, 2012. The PSC submits that this is not a representative case for the initial trial pool for the following reasons.

Plaintiff's counsel was deprived the opportunity to depose a sales representative, Robert Kesler, who had detailed Plaintiff's prescribing physician, Dr. Ottelin.[34] Plaintiff made multiple attempts to schedule Mr. Kesler's deposition, but AbbVie claimed that because Mr. Kesler was a Solvay employee who never came to Abbott, that they had no contact information for him, and were otherwise unable to locate him. As a result, Plaintiff was not able, and it appears may never be able to depose this sales representative. This will prevent Plaintiff from being able to fully discover this case on several important issues relating to how defendant marketed AndroGel. Therefore this case is not a representative trial pick.

[34] Mr. Kesler was not identified by AbbVie as a detailing sales rep in their original DFS for this plaintiff. However, it appears that Mr. Kesler was identified as having detailed Dr. Ottelin when AbbVie later discovered a cache of previously undiscovered call notes (that AbbVie failed to produce) dating back to the Solvay era, which was later produced to Plaintiff on April 8, 2016.

In addition, Mr. Cribbs' case possesses a unique causation element in that there is an issue of whether or not he had been taking a previously prescribed anticoagulant medication (Plavix) around the time of his injury because he received an epidural steroid injection to treat severe neck pain approximately two weeks prior to suffering his MI, which his doctor may have stopped his Plavix for around that time. Therefore, the question of whether Mr. Cribbs' MI was caused by his AndroGel usage or because he stopped taking his Plavix is a complicated and unique specific causation issue that will clearly be unique to his case.

3. Robert Cripe, No. 14-cv-00843:

Mr. Cripe is represented by Schachter, Hendy & Johnson. Plaintiff suffered a spinal cord infarction on February 21, 2011. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

First, Mr. Cripe's sustained devastating injuries that have rendered him paralyzed. The PSC appreciates that this kind of massive and catastrophic injury does not fall in the middle of the proverbial bell-curve. And because of this absolute fact, this case is not representative.

In addition, the thrombotic event (a spinal cord infarction) suffered by Mr. Cripe is an uncommon location for the blood clot involved to be located. Nearly all plaintiffs involved in this litigation who experienced a venous thrombotic event experienced either a DVT, PE or both.

Lastly, there is a complicated medical issue in this case as to whether Mr. Cripe's paralysis was in fact caused by a clot (the thrombosis), or whether it is the result of transverse myelitis (a neurological disorder involving inflammation of the spinal cord) caused by a virus. Surely this will involve a battle of experts, but unfortunately it will be an issue that has no

relevance for any other cases.[35]

4. Gene Dial, No. 15-cv-02190:

Plaintiff-decedent, Gene Dial, whose wife, Corliss Dial brought suit on his behalf, is represented by Anapol Weiss. Plaintiff suffered a MI March 15, 2013 and died the same day. The PSC submits that this is not a representative case for the initial trial pool for the following reasons.

At the time that Mr. Dial was prescribed AndroGel, he had extremely low testosterone; levels of only 3 ng/dl. Mr. Dial's testosterone levels were virtually non-existent and such a ridiculously low level is extremely atypical of the plaintiff pool. In fact, Mr. Dial's prescribing physician stated at his deposition that this was by far the lowest testosterone level he has seen in his entire career. Furthermore, Mr. Dial's testosterone level only went up to 194 ng/dl subsequent to his AndroGel use, which is still considered low, and is also unusual.

Furthermore, while the damages are compelling given this is a wrongful death case, because the PSC has already designated one wrongful death case for the initial pool, we do not believe having two wrongful death cases in the six case initial trial pool (which would result in 33.$5 of the pool being wrongful death cases) is representative of the overall percentage of wrongful death cases in the entire litigation.

Based upon the above factors, this case should not be selected as one of the six initial trial cases.

5. Theodor Diesslin, No. 14-cv-01086:

Mr. Diesslin, who is represented by Burg Simpson Eldredge Hersh & Jardine, P.C..

[35] AbbVie previously argued that Mr. Cripe's case was not representative in its Response to Plaintiffs' Bellwether Picks (Dkt No. 1055).

Plaintiff suffered a PE on September 10, 2012. The PSC submits that this is not a representative case for the initial trial pool for the following reasons.

Mr. Diesslin's case involves a unique injury claim that will involve novel issues of science. Mr. Diesslin claims that his PE exacerbated a vasovagal condition (sudden drop in blood pressure that can lead to fainting and other adverse effects), which he suffered from as a child. Since Mr. Diesslin suffered his PE, he has experienced multiple syncopal episodes associated with symptoms that he associates with his vasovagal condition, specifically feelings of nausea, fatigue, confusion and memory loss. The worsening of this condition has had a great impact on Mr. Diesslin's life, causing him to retire early. This is a unique fact pattern that is likely not present in any other case, and may result in extensive discovery beyond the facts related to Androgel's propensity to cause PE and is a sequela injury that is so unique that it will provide little, if any, value for the thousands of other TRT.

As the Court will recall, AbbVie and other Defendants made a motion in June 2014 to dismiss all cases from Texas and Michigan based on law that is unique to those States, which the Court denied. Mr. Diesslin is a resident of Texas. Undoubtedly, the issue in Defendants' motion to dismiss that is unique to Texas will be raised.

6. <u>Michael Ennis, Case No. 15-cv-00624</u>:

Mr. Ennis is represented by Seeger Weiss LLP. Plaintiff suffered a PE on July 5, 2007. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

Mr. Ennis is a resident of California, and has testified that he is a long time marijuana smoker, who currently has a medical marijuana license. He testified at deposition that he has tried other substances, and that he was "a real acid head" during his time in the army while

stationed in Guantanamo Bay in the late 1960s. While the relevancy of this testimony is questionable, defense counsel will likely attempt to trot it out as evidence that Mr. Ennis is a "risk-taker." This use of narcotics is not typical of the Plaintiffs in this litigation and selection of this case will require extensive motion *in limine* practice on the subject, and inject a distracting issue into the case that is not present in other cases. Mr. Ennis was 5'11" tall and weighed 270 lbs. Mr. Ennis was also on AndroGel for a relatively short time prior to suffering his injury. Mr. Ennis was only on AndroGel for two weeks prior to suffering his DVT. Although not a significant hurdle, this is likely much shorter than the typical AndroGel user.

7. Cecile Frost, No. 15-cv-01484:

Mr. Frost is represented by Pogust, Braslow & Millrood, LLC. Plaintiff suffered a Stroke on February 21, 2013. The PSC submits that this is not a representative case for the initial trial pool for the following reasons.

Mr. Frost's case is unique in that Mr. Frost has a history of alcoholism, alcohol-related legal troubles, a history of alleged domestic abuse, and admitted marijuana use in recent years including those contemporaneous with his AndroGel prescription. Mr. Frost's extensive personal history of battling addiction, and his criminal record are not representative of the plaintiff pool. These personal issues do not make this case representative nor will any result here be instructive given the unique personal issues that will surely impact so much of the final pre-trial and likely trial of this case.

Mr. Frost's case is also not instructive because his sworn testimony of using AndroGel on a daily basis from January 2012 through February 2013 appears to be inconsistent with the pharmaceutical records obtained by the parties to date. The pharmaceutical records currently in the possession of the parties do indicate that Mr. Frost began using AndroGel in January 2012,

but also suggest that the last point at which Mr. Frost filled an AndroGel prescription was for a 90-day supply in February 2012. Furthermore, the records of Mr. Frost's prescriber, Dr. Chow, include AndroGel as a current medication between January 2012 and February 2013 but also note an instruction that Mr. Frost "resume AndroGel" in January 2013. Based upon all of the foregoing, it is possible that the issue of whether Mr. Frost was using AndroGel contemporaneously with his injury will consume the trial and distract from the issues central to the litigation as a whole. As such, Mr. Frost's case is not suitable as a trial pick.

Mr. Frost is represented by Pogust, Braslow & Millrood, LLC. Plaintiff suffered a Stroke on February 21, 2013. The PSC submits that this is not a representative case for the initial trial pool for the following reason:

Mr. Frost's case is unique in that Mr. Frost has a history of alcoholism, alcohol-related legal troubles, as well as a history of alleged domestic abuse. Mr. Frost's extensive personal history of battling addiction, and his criminal record are not representative of the plaintiff pool. These personal issues do not make this case representative nor will any result here be instructive given the unique personal issues that will surely impact so much of the final pre-trial and likely trial of this case.

8. Froylan Garcia, No. 15-cv-01086:

Mr. Garcia is represented by Robert J. Debry & Associates, suffered a DVT on September 27, 2013. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

Mr. Garcia's case involves an issue concerning the date of the onset of his injury that renders it not representative as a bellwether trial case. Mr. Garcia began using AndroGel on May 17, 2013 and continued his use of the drug through September 2013. On September 27, 2013,

Mr. Garcia was seen at the Intermountain Vein Clinic for treatment of varicose veins. There, he underwent a Doppler ultrasound that revealed bilateral "chronic" DVTs. Despite the fact that Mr. Garcia had never been diagnosed with, or treated for, a DVT prior to September 2013, his diagnosing physician, Dr. Asay, testified at deposition that Mr. Garcia's DVTs were several months to a year old. Indeed, the fact that Mr. Garcia has such a unique case-specific issue, namely whether his injury pre-dated his AndroGel use makes this case not representative and a case that will likely not be instructive given this unique issue.

9. Kevin Hession, No. 14-cv-08222:

Mr. Hession is represented by Douglas & London, P.C.. Plaintiff suffered a DVT on October 23, 2012, and October 28, 2013.

Mr. Hession's unusual medical history and unique circumstances surrounding the diagnosis of his DVTs that are inapposite to the plaintiff pool as a whole. Mr. Hession has a history of multiple DVTs (even before his AndroGel use). The first of occurred in 2006 while he was in a coma as the result of Acute Disseminated Encephalomyelitis, an extremely rare neurological condition that causes intense inflammation in the brain and spinal cord. This first DVT was treated with the placement of an IVC filter. It is accepted within the medical community that IVC filters placement may cause subsequent thrombotic events. Thus, Mr. Hession's case involves the novel issue of whether his subsequent DVTs suffered while on AndroGel were the result of the placement of his IVC filter or the result of his AndroGel use. This causation issue is not common to the plaintiff pool.

Notwithstanding, Mr. Hession suffered a subsequent DVT in his left leg prior to initiating AndroGel on November 18, 2011, for which he was treated with Warfarin. Then, on October 23, 2012, approximately 8 months after initiating AndroGel, Mr. Hession underwent an ultrasound

that revealed the presence of a DVT in his left leg. This is an extremely complicated causation and damages issue that is unique to Mr. Hession's case.

Additionally, Plaintiff was unable to depose a sales representative in this case, Nicole Rossetti, who had detailed Mr. Hession's prescribing physician despite the issuance of a federal subpoena.[36] The failure of this sales representative to appear for her deposition, which deprived Plaintiff of his ability to fully discover this case, is yet another compelling reason why this case should not be selected as a trial pick.

10. Anthony Long, No. 1:14 –cv -6996:

Anthony Long is represented by The Levensten Law Firm. He suffered a stroke on December 20, 2013, at the age of 56. The PSC submits that this is not a representative case for the initial trial pool for the following reasons: He used AndroGel approximately from March 2010 to November 2013, and there is a potential issue regarding Mr. Long's use of AndroGel, as there is no written evidence of contemporaneous AndroGel use when he suffered his stroke. Plaintiff suffered a second stroke (after ceasing AndroGel usage four months prior), which resulted in permanent disability, and is now receiving Social Security Disability benefits. Plaintiff's recall and speech is limited due to strokes, and, as a result, has may have a difficult time testifying. This is not typical and may confuse the issues before the jury.

[36] Plaintiff's counsel originally requested Ms. Rossetti's deposition in March, and offered multiple dates on which it could take place in hopes of scheduling the deposition on a day that was mutually convenient for all of the parties. However, it was not until nearly three months later in June that a single date was offered for this deposition; a date that was not feasible for Plaintiff's counsel. After informing AbbVie's counsel that this date would not work, and asking that the deposition take place on a different date, AbbVie's counsel responded that Ms. Rossetti was now pregnant and unwilling to testify and a subpoena would need to be issued. A subpoena was issued for July 19, 2016, but Ms. Rossetti refused to appear for the deposition.

11. Randy Martina, No. 14-cv-08598:

Mr. Martina is represented by Weitz, & Luxenberg, P.C. Plaintiff suffered a MI on November 15, 2012 and a stroke on March 2014. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

First, during the core discovery, AbbVie raised an issue relating to that is not characteristic of the plaintiff pool. Mr. Martina's prescribing physician, Dr. Hovermale, testified that when she prescribed AndroGel to Mr. Martina, she instructed him to follow up regularly with an endocrinologist. She further testified that Mr. Martina did not follow up with an endocrinologist per her instructions, and, as such, his testosterone levels were not monitored during his AndroGel usage. This issue is not a central issue to other cases, and is so case-specific that it renders this case non-representative to the overall process for trial initial cases.

Second, Mr. Martina's lack of residual damages as the result of his stroke is atypical of most MIs and strokes. Mr. Martina has essentially no lasting damage from his MI and stroke. Mr. Martina testified at his deposition that he regularly runs 5k and 10k races, plays golf, lifts weights and bicycles. Mr. Martina's treating cardiologist, Dr. George confirmed Mr. Martina's lack of residual damage. This unusual lack of lasting damage as the result of Mr. Martina's cardiovascular and cerebrovascular injuries renders Mr. Martina's case unreflective of the ordinary MI and/or stroke case where there is some residual damage.

12. Jesse Patridge, Case No. 14-cv-7960:

Mr. Patridge is represented by Simmons Hanly Conroy. Plaintiff suffered a DVT January 12, 2011. The PSC submits that this is not a representative case for the initial trial pool for the following reasons.

Mr. Patridge has a significant and unique surgical history. Mr. Patridge has a history of

renal cell cancer for which he underwent a total nephrectomy. Although this surgery occurred over a decade ago, missing a kidney places Mr. Patridge at an increased risk of VTE to this day. Having only one kidney is a trait that is not at all representative of the plaintiff pool. A tremendous amount of time and effort will go into litigating the singular alternative causation issue presented by this unique medical history, which will not be instructive for very many**,** if any**,** of the remaining cases in the bellwether pool. Therefore, this case should not be selected as a bellwether trial pick.

13. Michael Romanik, No. 1:14-cv-08202:

Michael Romanik suffered a PE at the age of 46 on April 16, 2012. The PSC submits that this is not a representative case for the initial trial pool for the following reason:

At the time of his PE in April 2012, Mr. Romanik was 5'10" tall and weighed 250 lbs. Mr. Romanik apparently suffers from nephrotic syndrome, which the PSC expects that AbbVie will focus on at trial and which is not a common issue in other cases. This case turns on the abnormal scenario where dosage was decreased. Mr. Romanik used AndroGel as directed for a few months and returned to his doctor, who ordered another blood test, which revealed a testosterone level above the high limits for the lab. His doctor told Mr. Romanik to decrease his dosage from two pumps daily to one pump. Mr. Romanik's testosterone levels came to fall within normal limits within a month. Also, the deposition of the prescribing doctor could not be scheduled before the applicable deadline, which did not occur in other cases, but the PSC understands that Mr. Romanik's doctor was heavily detailed by AbbVie sales representatives (and AbbVie tried to recruit her as a speaker).

14. Robert Rowley, No. 15-cv-02760:

Mr. Rowley is represented by Robert J. Debry & Associates. Plaintiff suffered a DVT on

April 27, 2013. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

First, Mr. Rowley suffers from Crohn's disease, a rare inflammatory bowel disease that more than doubles a person's risk of having a DVT. Crohn's disease is a rare, but serious disease that affects only 0.5% of the population.[37] As such, it cannot be argued to be representative underlying condition in the plaintiff pool. As such, this factor takes away from this case's ability to serve in any representative capacity given the potential alternative causation factor that Crohn's disease may have played in plaintiff developing a DVT versus the use of AndroGel. And litigating this issue will have little, if any, impact on any other of the thousands of plaintiffs.

Secondly, Mr. Rowley had his left testicle removed because of a benign testicular tumor. Removal of a testicle is a radical procedure that is rare among the population of AndroGel users. As such, this case is clearly not representative and should not be selected as an initial trial case.

15. Dale Shepherd, No. 14-cv-00404:

Mr. Shepherd is represented by Robert J. Debry & Associates. Plaintiff suffered a DVT on March 7, 2011. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

Mr. Shepherd suffers from severe psychological illnesses. Mr. Shepherd suffers from severe depression, and has been hospitalized for attempted suicide. Additionally, he has received treatment for addiction. These are serious psychological conditions, which render him and thus case non-representative to a bellwether trial pool that is supposed to be instructive for thousands of other claimants. Having such strong and compelling psychiatric issues, which the PSC can

[37] *See, e.g.*, "The Facts About Inflammatory Bowel Diseases", Crohn's & Colitis Foundation of America, accessible at www.icff.org/assets/pdf/updatedibdfactbook.pdf.

reveal in further detail, under seal, are so unique that any result in this case would likely not be instructive and even worse, would inevitably create a mountain of work during motion *in limine* practice as well as potential sideshow at his trial that would be particular to his case.

Additionally, Mr. Shepherd has more than the average number of confounding physical ailments. Mr. Shepherd was morbidly obese (BMI of 38.1), he suffers from hypertension, high cholesterol, and has a history of Transient Ischemic Attacks, as well as a family history of thrombotic events. Based upon all of the above, Mr. Shepherd's case, and therefore is not representative as a bellwether trial pick.

16. Roccie Truax, No. 14-cv-02935:

Mr. Truax is represented by Levin Simes, LLP. Plaintiff suffered a MI on November 17, 2013. The PSC submits that this is not a representative case for the initial trial pool for the following reasons:

Mr. Truax is an opioid user as the result of severe back pain. Additionally, Mr. Truax's medical records contain positive indications for methamphetamines. While it is the Plaintiff's position that that these references in the medical records are false positives caused by Mr. Truax's sinus medications, this issue and medical history is nonetheless peculiar to Mr. Truax's case.

17. Joe Trusty, No. 15-cv-01015:

Mr. Trusty is represented by Levin Simes LLP. Plaintiff had a catheterization performed as the result of coronary artery disease on September 23, 2011. The PSC submits that this is not a representative case for the initial trial pool for the following reasons.

First and foremost, Mr. Trusty's case is simply not representative of the plaintiff pool because he never suffered a thrombotic event. Mr. Trusty has never been diagnosed with a MI,

stroke, DVT, or PE Mr. trusty's injury is neither a DVT or PE nor it is a MI or stroke, the injuries always contemplated by every version of CMO 14. Mr. Trusty simply suffered from coronary artery disease and required a catheterization. Rather, he has a history of coronary artery disease for which a stent was placed in 2007, and for which he underwent a subsequent catheterization in September of 2011 while he was on AndroGel. Mr. Trusty's injury and claims are unique and litigating this case through trial will be colossal waste of time and resources and will not be instructive for the thousands of other TRT and AbbVie only cases.

18. Dave White, No. 14-cv-03818:

Mr. White is represented by Janet Jenner & Suggs. Plaintiff suffered a MI on September 6, 2013 and died shortly thereafter.

Mr. White's case is not representative because it is a death case. It is one of only two death cases included in the pool of 32 initial bellwether picks, and one of only seven included in the random pool of 100 cases. Death cases present unique issues because of the lack of ability to examine the Plaintiff, which complicates causation and usage issues. As such, this is not a suitable case for an initial bellwether trial.

V. CONCLUSION

For the reasons set forth above, the Court should designate and select the cases set forth herein, in the proposed sequence, as the initial trial cases for the AbbVie only initial trials.

To obtain the greatest benefit from the bellwether process, the cases selected for bellwether trials should offer guidance to the majority of other cases in the litigation. Plaintiffs look forward to discussing this matter with the Court should Your Honor have any questions.

For the foregoing reasons, the PSC respectfully requests that the Court enter an Order setting the *Deel*, *Konrad*, *Mitchell*, *Blanck*, *Myers* and *Nolte* cases as the initial trial cases in this MDL.

Dated: July 25, 2016

Respectfully submitted,

/s/ Christopher A. Seeger

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Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2016, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to all parties by operation of this Court's electronic filing system. Parties may access this filing through the Court's system.

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EXHIBIT A

TRIAL-ELIGIBLE PLAINTIFFS IN THE BELLWETHER POOL

#	Plaintiff's Name	MDL NDIL Case No.	Firm Representing the Plaintiff	Injury
1	Blanck, Lance	15-cv-01077	Ross Feller Casey	PE/DVT
2	Cannon, Sr., Richard	15-cv-01835	Onder, Shelton, O'Leary & Peterson	DVT
3	Cribbs, Edward	15-cv-01056	Weitz & Luxenberg	MI
4	Cripe, Robert	14-cv-00843	Schachter Hendy & Johnson	Stroke or TE
5	Deel, David	14-cv-10435	Morgan & Morgan	MI
6	Dial, Gene	15-cv-02190	Anapol Schwartz	MI + death
7	Diesslin, Theodor	14-cv-06770	Burg Simpson Eldredge Hersh & Jardine	PE
8	Ennis, Michael	15-cv-00624	Seeger Weiss LLP	DVT
9	Frost, Cecile	15-cv-01484	Pogust Braslow & Millrood	Stroke
10	Garcia, Froylan	15-cv-01086	Robert J. Debry & Associates; Burg Simpson Eldredge Hersh & Jardine	DVT
11	Hession, Kevin	14-cv-08222	Douglas & London	DVT
12	Konrad, Jeffrey	15-cv-00966	Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.	MI
13	Long, Anthony	14-cv-06996	The Levensten Law Firm	Stroke
14	Martina, Randy	14-cv-08598	Weitz & Luxenberg	Stroke + MI
15	Mitchell, Jesse	14-cv-09178	Goldberg & Osborne	MI
16	Myers, Arthur	15-cv-01085	Ross Feller Casey	PE
17	Nolte, Robert	14-cv-08135	Goldberg & Osborne	PE
18	Patridge, Jesse	14-cv-07960	Simmons Hanly Conroy	DVT
19	Romanik, Michael	14-cv-08202	Ross Feller Casey	PE
20	Rowley, Robert	15-cv-02760	Robert J. Debry & Associates; Burg Simpson Eldredge Hersh & Jardine	DVT
21	Shepherd, Dale	15-cv-00404	Robert J. Debry & Associates; Burg Simpson Eldredge Hersh & Jardine	DVT
22	Truax, Roccie	14-cv-02935	Levin Simes	MI
23	Trusty, Joe	15-cv-01015	Levin Simes	CAD/Stent
24	White, Dave	14-cv-03818	Janet Jenner & Suggs	MI + death

EXHIBIT B

CASES EXCLUDED FROM TRIAL ELIGIBILITY BY COURT ORDER OR AGREEMENT OF THE PARTIES

#	Plaintiff's Name	MDL NDIL Case No.	Firm Representing the Plaintiff	Injury	Defense/Plaintiff/ Overlap/Random	Date & Manner Such Case was Excluded
1	Adkins, John	14-cv-09753	The Levensten Law Firm	PE/DVT	Defense	5/26/2016 - by agreement of the parties
2	Agard, Walter	14-cv-09742	TorHoerman Law	MI	Defense	4/21/2016 - by Court Order
3	Camp, Randall	15-cv-02243	Johnson Becker	DVT	Defense	4/21/2016 - by Court Order
4	Ferrer, William	15-cv-00345	Johnson Becker	PE/DVT	Plaintiff	11/20/2015 - by Court Order
5	Friedel, Jeffrey	14-cv-06512	Schachter Hendy & Johnson	PE/DVT	Plaintiff	4/21/2016 - by Court Order
6	Guy, Michael	14-cv-08894	Provost Umphrey Law Firm	Stroke	Plaintiff	4/21/2016 - by Court Order
7	LaForest, Kenneth	15-cv-00692	Seeger Weiss	MI	Random	7/21/2016 - by agreement of the parties
8	Palmer, Larry	14-cv-09325	Ashcraft & Gerel	MI	Defense	4/21/2016 - by Court Order
9	Roberts, William	14-cv-03062	Levin Simes	Stroke (hemorrhagic)	Defense	4/8/2016 - by agreement of the parties
10	Staton, Mark	15-cv-00619	Baron & Budd	Stroke	Plaintiff	4/21/2016 - by Court Order